REMARKS

The Office Action of May 22, 2009, has been received and reviewed.

Claims 1-16 and 18-23 are currently pending and under consideration in the above-referenced application. Each of claims 1-16 and 18-23 has been rejected.

Reconsideration of the above-referenced application is respectfully requested.

Claim Interpretation

The Office has interpreted independent claims 1 and 20 in such a way that a composition that *comprises* an extract of an egg, and may optionally include other components, is administered to a treated animal. Office Action of May 22, 2009, page 3. Specifically, according to the Office's interpretation of independent claims 1 and 20, in addition to the egg extract, the composition that is administered to a treated animal may include other components of an egg. *Id.*

Independent claims 1 and 20 have been amended to remove reference to a composition that includes an extract of an egg, and to more directly recite that *the extract is administered to a treated animal.* The extract that is administered consists of "water soluble proteins of a yolk of [an] egg... that have molecular weights of about 8,000 Da or less..."

Rejections under 35 U.S.C. § 102

Claims 1-16 and 18-23 have been rejected under 35 U.S.C. § 102.

A claim is anticipated only if each and every element, as set forth in the claim, is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). That single reference must show the identical invention *in as complete detail* and *in the same arrangement as that contained in the claim. Net MoneyIn, Inc. v. Verisign,* 545 F.3d 1359, 1369-70 (Fed. Cir. 2008) (emphasis supplied); *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Dopson

Claims 1-16 and 19-23 have been rejected under 35 U.S.C. § 102(e) for reciting subject matter that is purportedly anticipated by the subject matter described in U.S. Patent Application Publication 2002/0044942A1 of Dopson (hereinafter "Dopson").

The Office's indication that the 35 U.S.C. § 102(e) rejection based on Dopson may be overcome by filing an affidavit in accordance with the requirements 37 C.F.R. § 1.131 is gratefully acknowledged. Such an affidavit will be prepared and executed when all further issues in the above-referenced application have been resolved.

Lee

Claims 1-3, 7-13, 15, 16, and 18-23 have been rejected under 35 U.S.C. § 102(b) for being drawn to subject matter that is allegedly anticipated by the description provided by U.S. Patent 5,367,054 to Lee (hereinafter "Lee"), evidenced by U.S. Patent 5,470,835 to Kirkpatrick (hereinafter "Kirkpatrick").

Lee describes methods for purifying IgY from eggs. The processes that are taught in Lee are useful for obtaining IgY of 90% or greater purity. Lee describes a variety of different processes that may be used in purifying IgY from eggs, setting forth useful combinations of these processes in Fig. 1. The purified IgY of Lee may be used for pharmaceutical purposes or as a health food ingredient. Col. 3, lines 38-40. Thus, according to Lee, the *only composition* that is administered to a subject is *substantially pure IgY.*

Initially, the purification process described by Lee includes the separation of egg yolks from whites, followed by dilution, homogenization, and further dilution in a salt-containing buffer, further homogenization, then phase-separation of the egg yolks. Col. 5, lines 38-64.

As indicated in Fig. 1 of Lee, phase separation includes separation of an aqueous phase from a lipid phase. Lee refers to the lipid phase as a "precipitate phase," and notes that "phospholipids and other important functional and biologically active components" may be obtained from the lipid phase. Fig. 1; col. 5, lines 31-61. The aqueous phase includes IgY and, if present, transfer factor. The disclosure of Lee focuses on processing of the aqueous phase to provide a product which is suitable for administration to an animal.

Notably, each of the purification paths shown in Fig. 1 of Lee includes at least one process that would result in the removal of any transfer factor that might be present in the aqueous phase. For example, Lee describes an ultrafiltration step, a gel filtration step, and a desalting step.

In the ultrafiltration step, larger molecules, such as antibodies, are separated from smaller molecules, which would include any transfer factor present in the aqueous phase. Specifically, Lee describes that ultracentrifugation of an aqueous, antibody-containing solution may be effected with a filter having a molecular weight cutoff (MWCO) of either 30,000 Da or 100,000 Da. Col. 5, line 65, to col. 6, line 14. As the MWCO of the ultracentrifugation filter disclosed in Lee is much larger than the molecular weights of transfer factor molecules, which are known to be less than about 10,000 Da, any transfer factor that might have otherwise been present in the purified aqueous, antibody-containing solution would be separated from the larger antibody molecules, which have molecular weights of about 168,000 Da. As a result, the resulting composition, which Lee indicates may subsequently be administered to a mammal, would not include transfer factor.

Lee also describes that ion exchange chromatograpy, including anion exchange chromatography or cation exchange chromatography, may be used to purify IgY. Col. 6, line 15, to col. 7, line 2. In ion exchange chromatography, the solid phase of the column somewhat selectively binds side chains of the molecule of interest, in this case molecules that are to be removed from the final product. As is well known in the art and suggested in Lee, the binding selectivity of the column must be specifically tailored to capture the molecule(s) of interest. Transfer factor is a hydrophilic, polar molecule. *See* U.S. Patent 5,840,700 to Kirkpatrick et al., col. 2, lines 39-41. Therefore, the highly polar solid phase materials of the types described in Lee would, more likely than not, capture transfer any factor molecules, while IgY readily passes through such a column. *See,* Lee, col. 6, lines 47-55. Therefore, even if present in the eggs of Lee, transfer factor would not necessarily remain in Lee's product following purification with an ion exchange column.

At col. 7, lines 3-15, Lee describes use of precipitation processes in the purification of IgY. The precipitation methods that are described in Lee, which are similar to those described in

the above-referenced, result in the precipitation of IgY from solution, while much smaller proteins, such as transfer factor (if even present), remain in solution, which is to be discarded.

Gel filtration, another process that Lee describes may be useful in purifying IgY (col. 7, lines 16-24), is also effected on the basis of molecular weight. Lee describes that the compositions thereof need only include three components: γ-livetin (IgY), α-livetin, and β-livetin. As transfer factor molecules have smaller molecular weights than any of these desired molecules, if they were even present in the eggs of Lee, they would remain trapped in the pores of the gel beads of a gel filtration column longer than any of the desired molecules and, thus, would not be present in the resulting composition.

In the desalting step (col. 7, lines 25-37; col. 12, lines 40-58), which is necessary since the presence of salt (from initial separation) in the purified IgY will adversely affect antigen-binding, the aqueous, antibody-containing solution of Lee is dialyzed. The disclosure of Lee is limited to use of a dialysis membrane that has a MWCO of 12,000 Da to 14,000 Da. As the MWCO of the dialysis membrane taught in Lee is much larger than the molecular weights of transfer factor molecules, any transfer factor that may have otherwise been present in the aqueous, antibody-containing solution would pass through the pores of the dialysis membrane and, thus, be removed from the solution.

The result of the purificiation processes described by Lee is a composition that includes substantially pure IgY and no transfer factor (or very little, if any, transfer factor). Thus, when a composition resulting from the processes of Lee is administered to a mammal, that composition does not include transfer factor in a sufficient quantity to initiate a T-cell mediated immune response in the treated animal. Therefore, Lee does not does not expressly or inherently describe each and every element of the method recited by independent claim 1, as would be required for the Office to maintain its 35 U.S.C. § 102(b) rejections of independent claims 1 and 20.

Claims 2, 3, 7-13, 15, 16, 18, 19, and 22 are each allowable, among other reasons, for depending directly or indirectly from claim 1, which is allowable.

Claim 2 is further allowable since it is apparent from the purification techniques described in Lee that all molecules having molecular weights of about 4,000 Da to about 5,000 Da will be removed from the final, useful compositions.

Claims 10, 12, and 13 are each additionally allowable since Lee lacks any express or inherent description of administering a composition that includes transfer factor specific for at least one antigen of a pathogen.

Claim 18 is additionally allowable since Lee does not expressly or inherently describe that non-mammalian transfer factor may be administered to a treated subject.

Claim 19 is further allowable because Lee neither expressly nor inherently describes that, following administration of one of the compositions of Lee to a subject, transfer factor in the composition (there is none) "causes the treated animal, *in vivo,* to elicit [a] T-cell mediated immune response."

Claim 22 is also allowable since Lee includes no express or inherent description of "administering to [a] treated animal a sufficient quantity of [a] composition to enhance an ability of the immune system of the treated animal to elicit an increased T-cell mediated immune response . . ." Rather, the description of Lee is limited to administering compositions that include substantially purified antibodies, which cause the treated subject to elicit a B-cell immune response, not a T-cell mediated immune response.

Claim 21 is allowable, among other reasons, for depending directly from claim 20, which is allowable. Additionally, claim 21 is allowable since it is apparent from the purification techniques described in Lee that all molecules having molecular weights of about 4,000 Da to about 5,000 Da will be removed from the final compositions that Lee discloses are useful for administering to other animals.

In view of the foregoing, it is respectfully requested that the 35 U.S.C. § 102(b) rejections of claims 1-16 and 18-23 be withdrawn, and that each of these claims be allowed.

Rejections under 35 U.S.C. § 103(a)

Claims 4-6 and 14 stand rejected under 35 U.S.C. § 103(a).

There are several requirements in establishing a *prima facie* case of obviousness against the claims of a patent application. All of the limitations of the claim must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Even then, a claim "is not proved obvious merely by demonstrating that each of its elements was,

independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007). The Office must also establish that one of ordinary skill in the art would have had a reasonable expectation of success that the purported modification or combination of reference teachings would have been successful. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). There must also "be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.*, quoting *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006). That reason must be found in the prior art, common knowledge, or derived from the nature of the problem itself, and not based on the Applicant's disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006). A mere conclusory statement that one of ordinary skill in the art would have been motivated to combine or modify reference teachings will not suffice. *KSR* at 1396.

Lee in View of Taylor

Claims 4-6 have been rejected under 35 U.S.C. § 103(a) for being directed to subject matter that is assertedly not patentable over the teachings of Lee, evidenced by Kirpatrick, in view of the subject matter taught by U.S. Patent 5,001,225 to Taylor (hereinafter "Taylor").

Each of claims 4-6 is allowable, among other reasons, for depending from independent claim 1, which is allowable.

Lee in view of Dekich

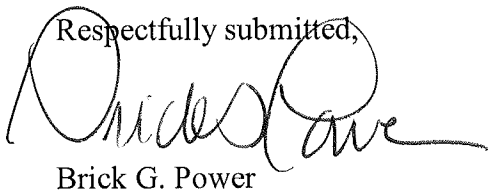
Claim 14 has been rejected under 35 U.S.C. § 103(a) for reciting subject matter that is allegedly not patentable over teachings from Lee, evidenced by Kirkpatrick, in view of the teachings of Dekich, M.A., "Broiler Industry Strategies for Control of Respiratory and Enteric Diseases, Poultry Sci., 77:1176-1180 (1998).

Claim 14 is allowable, among other reasons for depending from independent claim 1, which is allowable.

CONCLUSION

It is respectfully submitted that each of claims 1-16 and 18-23 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



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